

## REMARKS

Claims 1 to 22 are pending in this application and have been rejected under 35 U.S.C. § 102, 103, and 112 as being unpatentable. Reconsideration is requested for each of these claims.

### Election/Restriction

Applicant notes that the Examiner has maintained the restriction requirement and has withdrawn claims 23-52 from further consideration as a nonelected Group.

### Claim 1

#### 35 U.S.C. § 112

Claim 1 has been rejected under 35 U.S.C. § 112, first and second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention,” and “as not enabling”. While the Examiner argues that the specification provides for the reduction of hair growth, and not the increase of hair growth, Applicant does not concede to this characterization. However, Applicant has amended claim 1 without prejudice and believes amended claim 1 overcomes this rejection.

Further, the Examiner rejected Claim 1 under 35 U.S.C. § 112, first paragraph because “the specification... does not reasonably provide enablement for the treatment of the hair with any extract from botanical families such as leguminosae, solanaceae, gramineae or cucurbitaceae.” Applicant traverses this rejection.

Although the Examiner has argued that “[u]ndue experimentation would be placed on an artisan of ordinary skill in the art to extract the literal thousands of plant species claimed and topically applying said extract to determine the pharmacological effects,” undue experimentation is not required to determine a claimed compound has the desired pharmacological effects. The patents attached as Exhibit A each have a limited number of working examples, and yet their

claims include the terms, *leguminosae*, *solanaceae*, *gramineae* or *cucurbitaceae* ("Plants"), evidencing that undue experimentation is not required to determine whether any of these Plants have the desired pharmacological effects. If the Examiner is aware of references which show that methods using these Plants or their extracts are not routine and predictable at this time, the Examiner is asked to cite them. If such facts are within the Examiner's personal knowledge, the Examiner is requested to make them part of the record by way of affidavit as required by 37 C.F.R. § 1.104 (d)(2).

Applicant respectfully submits that so long as the experimentation required for practicing the invention is routine, the extent of such experimentation is immaterial to § 112 requirements. The Federal Circuit supported Applicant's view in *In re Wands*, 8 U.S.P.Q.2d 1400, 858 F.2d 731 (Fed. Cir. 1988), which stated the test whether experimentation required to practice an invention is undue,

is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

*In re Wands*, 8 U.S.P.Q.2d 1400, 858 F.2d 731 (Fed. Cir. 1988)

In order to practice the *Wands* invention, extensive (but not undue) experimentation was required, but this did not preclude a finding that the *Wands* claims were enabled. Therefore, since Applicant's claims do not require undue experimentation, Applicant's claims are still enabled. The specification teaches what the invention is and how to use it, so that one skilled in the art can practice the invention as claimed without the burden of undue experimentation, and § 112 is satisfied. If the Examiner believes that it would be qualitatively un-routine to duplicate the Applicant's invention based upon the specification, Applicant invites the Examiner to cite evidence or offer a declaration to this effect.

Claim 2

Claim 2 has been amended, without prejudice, and Applicant has addressed the insufficient antecedent basis rejection.

Claim 18

The Examiner rejected claim 18 because the “specification, which enabling for treatment of pseudofolliculitis barbae, does not reasonably provide enablement for its prevention.” Applicant traverses this rejection.

The specification of the Application clearly teaches “a method to reduce or prevent pseudofolliculitis barbae.” Pseudofolliculitis barbae is characterized by curly, disorganized, inward hair growth. (Seiberg Declaration ¶1, attached as Exhibit B). Applicant notes that the method for treatment of pseudofolliculitis barbae involves the reduction of facial hair growth, hair follicle and shaft size and the promotion of growth of more directionally organized hair. By doing so, further incidence of pseudofolliculitis barbae is prevented (Seiberg Declaration, ¶1), and therefore the specification enables both the treatment and prevention of the hair disorder.

35 U.S.C. § 102 Anticipation

The Examiner rejected claims 1-22 as being anticipated by Kose Corp. (JP 5-25027) (“Kose”). Kose allegedly “reads on the topical application of an extract of the cucurbitaceae family, useful as a hair growth inhibitor[; and] that said extract inherently contains serine protease inhibitors and isoflavones[.]” Applicant traverses this rejection for the following reasons.

It is known in protein biochemistry that the conformation of proteins, namely their native tertiary and quaternary structures, are important to their activities. The conformation of proteins is largely dependent on weak bonds, which are very sensitive to changes, notably, the

hydrophobic R groups of the amino acids of proteins tend to be close to each other at the interior of the folded protein, in order to be as far away as possible from the aqueous environment of living cells. *See, e.g.* Keton & Gould, eds., Biological Sciences, 4<sup>th</sup> ed., Chapter 3, p. 66-67 (1986). Hydrophobic solvents (e.g. hexane, or 70 % v/v ethanol) will expose these groups, changing the proteins' native structure and in loss of activity. Applicant notes in the specification that Kose teaches "extracting solvents" in paragraph [0008] which are non-polar, and hydrophobic. Additionally, once proteins are denatured, they are no longer biologically active. *See, Biological Sciences*, p. 66. Kose teaches heat in the extraction, which causes protein denaturation. Therefore, the extracting solvents and the heat will destroy STI's activity.

Additionally, non-polar, hydrophobic solvents do not extract the STI, which are necessary for the present invention. Given that hydrogen bonds are weaker than the covalent bonds of the polypeptides, and the atoms in a protein that are hydrogen bonded to each other could as easily be hydrogen-bonded to water, the proteins could be solubilized in water, but not organic solvents. *See Doolittle, The Molecules of Life, Scientific American*, p. 42 (1985). This leads to the conclusion that the Kose extracting solvents cannot extract STI from any mixture.

Applicant has tested different solvents in extracting the STI. Trypsin inhibition is greatly decreased with an increase in ethanol in an ethanol/water mixture. (Seiberg Declaration, ¶2 and Exhibit 2). Thus, Kose's use of ethanol as an extraction solvent teaches away from the present invention in paragraph [0014] because this would prevent sufficient trypsin inhibition. "75 weight-parts of the 70% v/v% ethyl alcohol" has too low polarity to extract the STI and too much alcohol, which will denature the compound. The present invention requires an extract in which "the serine protease inhibitory activity ...will be retained," and "preferably that the protein STI will remain intact," and the extract in Kose will not meet these requirements.

35 U.S.C. § 103 Non-Obviousness

Claims 1-22 were rejected under 35 U.S.C. 103 (a) as being unpatentable over by Kose or Styczynski (U.S. Patent No. 5,958,946) (“Styczynski”). Applicant respectfully traverses this rejection.

As discussed in the anticipation rejection, Kose does not teach the present invention, and in fact teaches away from the present invention by using an excess of ethanol in extracting compounds from the cucurbitaceae family.

The Examiner additionally argues that Styczynski “teaches the topical application of an isoflavone to reduce hair growth [and] one of ordinary skill in the art would have expected an additive effect (i.e. reduction of hair growth) with the combination of one or more agents known to reduce hair growth.” Styczynski teaches modulation of “hair growth by topical application of a compound that induces or activates the conjugation of an androgen.” Col. 2, line 8-9. Use of Styczynski’s invention purports to reduce hair growth in androgen-stimulated areas, but that use in an area that has reduced hair growth in the presence of androgens will cause an increase in hair growth. Col. 2, Lines 15-30. Applicant’s invention is very different from Styczynski’s because the present invention will reduce hair in both types of areas. Beard hair is androgen sensitive but leg hair is not androgen sensitive (*see*, Thornton, Effect of Androgens on the Growth of Cultured Human Dermal Papilla Cells Derived From Beard and Scalp Hair Follicles, J. Invest. Derm., 97:2, 345-8 (Aug. 1991)), yet the present invention operates the same way in both, for example, reducing hair growth in both the leg and beard area.

Further, the present invention is distinct from Styczynski’s invention because unlike Styczynski, the present invention does not affect the hormone pathway. Styczynski’s invention employs hormone pathways as described by the correlation of specific effects in androgen-

stimulated areas and the opposite specific effects in androgen-reducing areas. Col. 2, lines 15-20. One of ordinary skill in the art would know that androgens and STI have different distinct pathways (Seiberg Declaration, ¶3). STI are not documented to affect the androgen pathway, unlike Styczynski's invention.

Therefore, it would be nonobvious to one of ordinary skill in the art to use STI to effect hair growth as claimed in the Application.

### CONCLUSION

Applicant respectfully asserts that the application is in condition for allowance.

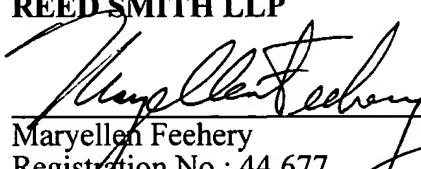
Reconsideration and the early issuance of a Notice of Allowance are requested.

#### Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees or credit any overpayment, to Deposit Account 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application.

Respectfully submitted,

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